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## **DEVICE FOR THE PRODUCTION OF FOAM IN A SYRINGE BODY**

The present invention relates to a device for the production, inside the body of a syringe, of a foam formed from gas bubbles in a surfactant liquid such as a composition intended for sclerotherapy comprising a surfactant sclerosing agent, this foam being intended to be administered by the parenteral route for therapeutic and/or cosmetic purposes in the human or animal body.

It is known that the injection of a sclerosing agent in the form of a foam for the sclerotherapy of varicosities or varices has important advantages (cf. "Sclerosing treatment of the saphenous veins and their large accessories using the MUS method" A. MONFREUX, *Phlebology* 1997, 50, no. 3, 351-353).

Nevertheless, this technique imposes the use of glass syringes in which the foam may be formed by blocking off the syringe body after drawing a liquid dose then traction on the piston, whereby air is introduced into the syringe body at the place of contact between the glass piston and the syringe body which is impermeable to liquids but not perfectly hermetic. A slight escape of air can in fact be created between the piston and the glass syringe body by means of a manual action on the piston.

This technique has several drawbacks: the glass syringes pose problems of hygiene and have to be sterilised, and it is not possible to use throwaway plastic syringes whose pistons are perfectly hermetic; the formation of the foam necessitates manipulations and the acquisition of a certain skill (force and speed of drawing on the piston) to obtain a homogeneous foam in the syringe; the characteristics of the foam obtained depend on the skill of the operator and on the properties of the liquid and on the syringe and are therefore not optimized as a function of the later therapeutic use of the foam. In particular, the foam is generally formed from relatively large bubbles and is not stable over time. Now, it is often desirable, particularly in the case of sclerotherapy, to form a foam with as

fine as possible bubbles whose stability over time is as great as possible so as to permit the holding of the foam in the vein area to be treated for as long as possible.

The invention thus aims at getting round these drawbacks by proposing a device allowing a foam to be produced from a surfactant liquid in a syringe which may also be a throwaway syringe or a glass syringe simply and rapid, the foam having homogeneous characteristic, scarcely dependent on the operator and capable of being optimized according to the intended therapeutic and/or cosmetic application.

The invention aims more particularly at proposing a device allowing a fine and stable foam to be obtained in a syringe and particularly a device adapted for sclerotherapy with the aid of a foam of sclerosing composition.

The invention also aims at proposing such a device that is simple, inexpensive, which may be made in a throwaway form, particularly from synthetic material, and packed in a sterile manner.

To do this, the invention relates to a device for the production inside the body of a syringe of a foam made up of gas bubbles in a surfactant liquid intended to be administered by a parenteral route, characterized in that it comprises a liquid drawing end piece with formation of foam, this end piece comprising:

- means of connection of the end piece to the body of a syringe,
- a drawing extremity adapted to be capable of being placed in contact with the liquid and allowing the drawing of the liquid under the effect of aspiration resulting from the manual operating of the piston of the syringe (in traction in the direction of its extraction out of the syringe body),
- means, called foaming means, capable of bringing about the instant formation of a foam from the drawn liquid and from the aspiration resulting from the manual operation of the piston of the syringe, these foaming means comprising means for introducing a gas in contact with the drawn liquid to form the foam.

Various embodiments may be considered for the foaming means. One may thus use any device

allowing a foam to be made from a surfactant liquid and gas under the effect of aspiration. In all of the present application, the term "gas" designates any gaseous phase. The gas used is adapted so that it can form a foam with the surfactant liquid. In most cases, the atmospheric air may be used, but the invention is also applicable for obtaining a foam with other gases.

It should be noted that the foaming means must be compatible with the connection of the drawing end piece to a syringe and must be capable of operating by aspiration of the liquid and gas under the effect of the negative pressure resulting from traction exerted on the piston of the syringe.

Advantageously and according to the invention, the foaming means comprise at least one plug of fibrous and/or porous and/or microperforated material, permeable to the surfactant liquid and the gas, and adapted to be able to be placed in contact with drawn liquid and with a gas source and to produce, under the effect of manual operation of the piston of the syringe, the foam which is formed instantly upon crossing the plug in a conduit or a cavity communicating with the inside of the body of a syringe connected to the drawing end piece by a means of connection.

The inventor has in fact ascertained that a simple plug made from fibrous and/or porous and/or microperforated material allows a foam of excellent quality to be formed in the syringe. This plug is adapted to be permeable to the liquid, gas and to the foam formed and is arranged so that it can be crossed by the drawn liquid and by the gas.

Advantageously and according to the invention, such a plug may be formed from cotton - particularly a hydrophilic cotton wad plug - or from a block of solid porous material - particularly a solid hard or soft foam.

The plug is adapted so that it can be crossed by the liquid, gas and the foam formed, and this at least under the effect of the aspiration resulting from the operation of the piston of the syringe.

According to the nature of the surfactant liquid and the gas used, the number, nature and dimensioning of the plug(s) may vary. In order to be permeable to the liquid, the gas and the foam formed, each plug comprises numerous crossing passages (channels, perforations, pores, interstitial spaces between fibres). Advantageously and according to the invention, at least one part of these

crossing passages has, in cross-section, dimensions markedly greater than a minimum dimension allowing the formation of a foam to be achieved. These dimensions are notably greater than the critical minimum diameter of the gas bubbles capable of being formed in a foam of the surfactant liquid. It is known, in fact, that the gas bubbles capable of being formed in a foam of surfactant liquid cannot have a diameter less than a critical minimum diameter which depends on the characteristics of the liquid and of the gas, and particularly on the surface tension of the liquid in the presence of the gas. In order to permit the formation of the foam upon crossing through the plug, the latter must have crossing passages allowing gas bubbles to pass and thus having dimensions greater than a minimum dimension corresponding to this critical minimum diameter and below which the foam does not form. Moreover, the dimensions and the number of crossing passages must be adapted to allow aspiration of the liquid and the gas through the plug under the effect of the negative pressure resulting from the manual operation of the piston of the syringe.

Generally speaking, a sole plug, homogeneous in its nature and dimensions, is sufficient to obtain a suitable foam.

Nevertheless, in order to improve the quality of the foam formed, one can also provide several successive plugs, the first having crossing passages of large dimensions to form a rough foam (with large bubbles), the following one(s) refining the foam (reducing the size of the bubbles) and thus revealing crossing passages of smaller dimensions. The average dimension of the crossing passages diminishes in the direction of flow of the composition during drawing, i.e. from the drawing extremity towards said means of connection of the drawing end piece. These different plugs may be stacked in contact with others, indeed may be one-piece to form only a single multi-layer block, or in contrast be separated from each other by at least one free space. For example, a first plug may be provided at the drawing extremity - particularly to form this drawing extremity - and another, finer one, in said means of connection.

In an advantageous embodiment, and according to the invention, the drawing end piece comprises a tube the end of which communicates with the body of the syringe through the means of connection.

Advantageously and according to the invention, the foaming means comprise a plug linked to the end of the tube that is opposite the means of connection in order to form said drawing extremity. The plug thus itself forms the drawing extremity. The tube and the means of connection are impermeable so that a traction exerted on the piston has the effect of drawing the liquid if part of the plug is immersed in the liquid whilst another emerges and is in contact with the gas, for example, the ambient air and/or to form the foam and to entrain it into the tube towards the syringe body.

Advantageously and according to the invention, the plug is spongy and adapted to draw instantly by soaking in the liquid and capillary action a predetermined quantity of liquid. The plug then does duty not only as a foaming means but also as a liquid drawing and dosing means. To do this, the plug is advantageously formed from a hydrophilic cotton ball wad and/or a spongy porous solid foam such as a sponge made of soft synthetic material or of natural origin at least in the soaked state.

The spongy plug swells with liquid when it is immersed in the liquid. Advantageously and according to the invention, the plug is adapted to present, when dry, dimensions of a width less than those of a liquid vessel neck (injectable solution ampoule) in such a way as to permit its introduction into such a vessel and, once soaked with liquid, dimensions in width greater than those of a liquid vessel neck (injectable solution ampoule) in such a way as to prohibit its untimely extraction outside the vessel.

The drawing end piece according to the invention may be fitted only with this plug forming the drawing extremity. As a variant, the drawing end piece may comprise at least one other plug of fibrous and/or porous material, for example another plug incorporated in the means of connection, particularly in a bottom cavity of a truncated female connector forming these means of connection, or another plug incorporated in a chamber placed between a tubular drawing extremity and the means of connection.

Advantageously and according to the invention, in an embodiment, the drawing end piece comprises a chamber placed between the means of connection and the drawing extremity in communication with the means of connection and the drawing extremity, and enclosing at least one

plug of fibrous and/or porous and/or microperforated material.

In an advantageous embodiment, and according to the invention, the means of connection of the drawing end piece comprise a cavity receiving the liquid drawn from the drawing extremity, and the foaming means comprise a gas outlet in the cavity. Advantageously and according to the invention, the cavity receives the liquid through an orifice issuing into the cavity and the effective cross-section of the gas outlet is less than that of this orifice. Advantageously and according to the invention, the foaming means comprise at least a plug of fibrous and/or porous and/or microperforated material placed in the cavity.

Moreover, advantageously and according to the invention, the drawing extremity is fitted with a filter adapted to prevent the aspiration of solid impurities.

The device according to the invention may present itself solely in the form of the drawing end piece, the vessel and the syringe being packed and supplied separately. In this case, the device according to the invention is made up of the drawing end piece. Thus the invention relates to such a drawing end piece.

Nevertheless, a device according to the invention may also advantageously comprise a vessel for liquid comprising a neck by which the drawing end piece may be introduced, for example, a glass prescored ampoule containing an injectable solution. As a variant or in combination, a device according to the invention may also advantageously comprise a syringe adapted so that it can be connected to the drawing end piece.

The device according to the invention advantageously presents itself in the form of a kit of different parts packed together comprising on the one hand, a drawing end piece fitted with foaming means and capable of being connected to a syringe body and, on the other hand, a vessel containing the liquid used to form the foam in the syringe body and/or a syringe itself (body and piston) made of glass or throwaway. The device according to the invention is advantageously a complete device in the form of a ready-to-use kit, for the parenteral administration of a foam made up of gas bubbles in



a surfactant.

Moreover, advantageously and according to the invention, the device also comprises a needle for the injection into the human or animal body of the foam previously formed in the syringe body. This needle is fitted with means of connection to the body of a syringe, particularly a truncated female connector. Advantageously and according to the invention, this needle comprises at least one solid element permeable to the foam - particularly a plug of fibrous and/or porous and/or microperforated material - inserted in the means of connection and adapted so that it can be crossed by the foam before its passage into the channel of the needle. Advantageously and according to the invention, the solid element is formed from a plug of cotton - particularly of a hydrophilic cotton wad plug.

The invention is advantageously applicable for sclerotherapy. The device according to the invention is then characterized in that the liquid is a composition intended for sclerotherapy comprising a surfactant sclerosing agent. The device according to the invention is thus a device intended for the administration by intravenous injection of a composition intended for sclerotherapy in the form of a foam.

The invention relates also to a device characterized in combination by all or part of the characteristics mentioned above or below.

Other aims, characteristics and advantages of the invention will appear upon reading the following specification that refers to the attached figures in which:

- figure 1 is a schematic view of a first embodiment of a device according to the invention,
  - figure 2 is a schematic view illustrating the device in figure 1 in the course of use,
  - figure 3 is a detailed schematic view in axial section of the drawing end piece of the device in figure 1.
- figures 4a to 4e are schematic views in axial section illustrating five successive stages respectively of a method of using a device according to a second embodiment of the invention.
- figures 5, 6 and 7 are schematic views in axial section illustrating respectively three other

embodiments of a device according to the invention.

- figure 8 is a schematic view illustrating the device in figure 8 in the course of use for the injection of foam,

- figures 9 and 10 are schematic views similar to figures 1 and 2 representing another embodiment of a device according to the invention,

- figure 11 is a schematic view representing the device in figure 9 in the course of a foam formation stage in the syringe body,

- figure 12 is a schematic view illustrating the device in figure 9 in the course of use for parental administration.

The device according to the invention represented in figure 1 comprises a syringe 1 for parenteral administration, particularly intravenously, of injectable therapeutic and/or cosmetic compositions. This syringe 1 may be a glass syringe or a throwaway syringe made of synthetic material comprising a cylindrical syringe body 2 and a piston 3 sliding in the syringe body 2, and equipped with an actuating extremity extending outside the syringe body. In the whole text, "piston" means the mobile unit inside the syringe body 2 doing duty as a manually operated pumping means. In the case of a throwaway syringe, the piston 3 is formed from a flexible waterproof seal and a piston rod extending axially from the seal to the outside of the syringe body 2. In the case of a glass syringe, the piston 3 is formed from a glass cylinder sliding in the syringe body 2.

The syringe body 2 comprises a truncated male connector 4 with an axially pierced extremity (the crest of the truncated cone being oriented axially towards the outside of the syringe body 2). This male connector 4 is adapted to allow the connection of an injection needle 5 fitted with a truncated female connector 8 of combined shape. It should be noted that the forms and dimensions of these truncated syringe and needle connectors 4, 8 are standard and well known per se.

The device according to the invention also comprises a liquid drawing end piece 7 with foam

formation. In a first embodiment shown in figures 1 to 3, the drawing end piece 7 comprises a truncated female connector 6 adapted so that it can be connected to the male connector 4 of the syringe body 2 in a combined form, forming a separable waterproof union. This female connector 6 is extended by a hollow rigid tube 9 whose length is adapted as a function of the depth of a vessel 10 containing the liquid to be drawn. The tube 9 carries, at its extremity 12 opposite the connector 6, a plug 11 formed from a hydrophilic cotton wad plug. The tube 9 is hollow and defines an internal longitudinal conduit of which one extremity 22 issues into the female connector 6 and is in communication with the body 2 of the syringe 1 to which the end piece 7 is connected.

The plug 11 is fixed to the extremity 12 of the tube 9, for example by tight windings, in the manner of the wad plugs applied to the two ends of the ear cleaning buds of the rod-cotton type (registered trademark). Tube 9 is preferably made from synthetic material. The extremity 12 of the tube 9 to which the plug 11 is linked is fitted with a filter 13 avoiding the ascent of any impurities (particularly cotton) into the tube 9.

It should be noted that the plug 11 is arranged in such a way as to extend beyond the extremity 12 of the tube 9 over an adequate height so that this plug 11 can be partly immersed in the liquid to be drawn whilst the extremity 12 of the tube 9 remains above the horizontal level of the liquid (figure 3). In this way, when a traction is exerted on the piston 3 of the syringe (tending to withdraw it from the body 2) after having connected the drawing end piece 7 to the body 2 of the syringe, the plug 11 being partly immersed in the liquid, a foam is instantly formed inside the syringe body 2 from the liquid drawn into the vessel 10 and from the atmospheric air penetrating the tube 9 via the plug 11 by its emerging part. The wad plug 11 therefore has the function of bringing about the instant formation of the foam from the liquid and the atmospheric air drawn by the aspiration resulting from the actuation of the piston 3 of the syringe. This foam is delivered to the exit of the plug 11 in the conduit 24 of the tube 9 communicating with the inside of the body 2 of the syringe 1 connected to the drawing end piece 7 through leakproof means of connection 4, 6.

In this first embodiment, advantageously and according to the invention, the drawing end piece

7 are in the general form of a cannula. The plug 11 linked to the free extremity 12 of the tube 9 forms one drawing extremity of the drawing end piece 7.

Generally speaking, this extremity plug 11 is sufficient to obtain a good quality foam. it should be noted, however, that according to a variant of the invention, a second plug, similar to the extremity plug 11, may be incorporated in the female connector 6, placed between the orifice issuing into the conduit 24 of the tube 9 in the female connector 6, and the free extremity of the male connector 4 of the syringe body 2. This second plug is preferably finer than the first plug 11 and has the function of refining the foam.

Once the foam has formed inside the syringe body 2, it is sufficient to separate the drawing end piece 7 and to replace it by a needle 5 for the purpose of injecting the foam with the aid of a syringe 1 into the human or animal body (figure 8).

In the second embodiment shown in figures 4a to 4e, the drawing end piece 7 comprises, at the extremity of the tube 9, a plug 14 formed from a spongy porous material adapted to draw instantly and meter by soaking in the liquid and capillary action a predetermined quantity of liquid. Thus, the plug 14 in this embodiment has a double function: on the one hand, it permits drawing of a predetermined dose of liquid and on the other hand it permits, as in the first embodiment described above, the instant creation of the foam inside the body of the syringe. This plug 14 may be formed from a porous soft solid block of foam with open cells, spongy, natural or synthetic, linked to the extremity 12 of the tube 9, for example by gluing and/or forcible insertion of this extremity 12 of the tube 9 into the block of foam 14.

The figures 4a to 4e show the procedure implemented to create the foam in the syringe body 2 with a device according to this second embodiment of the invention. Initially, the plug 14 is dry and has a width less than that of the neck 15 of the vessel 10, which, in the example shown, is a prescored ampoule of injectable composition. After having broken the ampoule 10 to open the neck 15, the drawing end piece 7 may be introduced into the ampoule 10, the plug 14 being dry and adapted so

that it can pass through the neck 15, and be immersed in the liquid. In this way, the plug 14 is soaked with liquid mainly by capillary action, no traction being exerted on the piston 3. If this is considered appropriate, a slight traction may nevertheless be exerted on the piston to facilitate the absorption of the liquid in the plug 14. When this is done, the volume of the plug 14 increases. In particular, its width increases to a value that is preferably greater than that of the neck 15 so that this plug 14, once soaked, cannot be extracted untimely from the vessel 10. Moreover, by raising the syringe 1, the plug 14 may be brought outside the liquid, a predetermined dose of liquid being drawn inside this spongy plug 14 (figure 4d). In the later stage (figure 4e), it is sufficient to exert a traction on the piston 3 of the syringe, which causes air to be admitted through the pores of the spongy material of the plug 14, and the formation of a foam inside the body 2 of the syringe.

It should be noted that the commercial ampoules 10 of injectable solution have standard dimensions so that the dimensions of the plug 14 may be adapted to those of these ampoules 10, particularly of their neck 15.

It should be noted that one may also use, as a variant, the first embodiment of figures 1 to 3 according to the procedure shown in figures 4a to 4e to form the foam in the syringe body 2. The plug 11 (formed from a hydrophilic cotton wad plug) is then immersed in the liquid to soak it with a dose of liquid by capillary actions (without exerting traction on the piston), then the plug 11 is removed from the liquid and a traction exerted on the piston 3 to introduce the air crossing through the plug 11 and forming the foam in the tube 9.

In the embodiment shown in figure 5, the drawing end piece 7 is made up of a truncated female connector 6 connecting to a syringe body 2 and a plug formed from a porous, soft or hard foam block 16. The extremity of the female connector 6 is directly linked to the foam block 16, particularly by gluing and/or welding and/or forcible insertion. In this embodiment, the drawing end piece 7 therefore does not comprise a tube. It is sufficient to immerse partly the foam block 16 which

does duty as a drawing extremity and to exert a traction on the piston 3 to form a foam inside the female connector 6 and in the syringe body 2. As a variant, if the plug 16 is spongy, one may also proceed as in the embodiment of figures 4a to 4e by previously immersing the plug 16 in the liquid, and only exerting a traction on the piston 3 after having withdrawn the soaked plug 16.

In the embodiment in figure 6, the female connector 6 of the end piece 7 is extended by a plug formed from a block of foam 17 cut to a point at least markedly in the extension of the taper of the female connector 6. A reinforcing tube 18 is provided, extending from the female connector 6 with which it communicates inside the foam block 17 to facilitate the assembly and to consolidate it. This tube 18 may be formed, for example, from a portion of metal injection needle or from a hollow tube made of synthetic material.

In the embodiment shown in figure 7, and contrary to the embodiments previously described, the drawing extremity is not formed by a plug of fibrous and/or porous material. In fact, in this embodiment, the free extremity 12 of the tube 9, preferably fitted with an anti-impurity filter 13, itself constitutes the drawing extremity of the drawing end piece 7 intended to be immersed in the liquid.

The truncated female connector 6 of the drawing end piece 7 is not strictly watertight and comprises at least one gas admission crossing orifice 19 arranged close to the junction of the female connector 6 with the tube 9. In the embodiment shown, a single orifice 19 is provided and is generally sufficient. If necessary, several orifices 19, preferably regularly distributed around the axis of the female connector 6, may be provided.

Preferably, this orifice 19 has a shape at least mainly convergent/divergent so as to create a Venturi effect. The orifice 19 issues into a cavity 20 of the female connector 6 enclosing a plug 21 of fibrous and/or porous material (hydrophilic cotton wad plug, soft or hard foam...). This orifice 19 thus constitutes a gas outlet (atmospheric air) in the cavity 20 which receives the liquid through an orifice 22 of the tube 9 also emerging into the cavity 20. The effective cross-section of the orifice 19

is less than that of the orifice 22 issuing from the tube 9, i.e. than the cross-section of the conduit 24 of tube 9. For example, the diameter of the conduit 24 of the tube 9 may be in the order of a millimetre whilst that of the effective cross-section (smaller cross-section) of the orifice 19 is in the order of one tenth of a millimetre, even less, according to the nature and density of the plug 21. If the free extremity 12 of the tube 9 is immersed in the surfactant to be drawn, and a traction is exerted on the piston 3 of the syringe, it is ascertained that a foam is formed inside the body 2 of the syringe. This foam is actually formed in the plug 21 and is delivered into the cavity 20 immediately opposite the extremity issuing from the male connector 4 of the syringe.

This embodiment also has the advantage of a better protection of the plug 21 incorporated in the female connector 6, with respect to contamination by contact with foreign bodies after unpacking. Moreover, the qualities of the foam formed may be adjusted, not only as a function of the characteristics of the plug 21 (fineness or density) but also as a function of the number of air admission orifices 19 and of the tube 9, and of the shape of each air admission orifice 19.

In the embodiment shown in figures 9 and 10, the drawing end piece 7 comprises a chamber 25 placed between the truncated female connector 6 and the drawing extremity 12. This chamber 25 encloses at least one plug 26 of fibrous and/or porous and/or microperforated material (hydrophilic cotton wad plug, solid foam block ...).

The chamber 25 is extended axially opposite the female connector 6 by a tube 9 whose free extremity 12 forms the drawing extremity 12. This extremity is truncated and male so as to do duty as a truncated male connector capable of receiving the female connector 8 of an administration needle 5. The chamber 25 is in communication with the female connector 6 and with the tube 9. It is preferably made from transparent synthetic material and may be fitted with graduations in the manner of a pipette.

In order to use this device, the drawing extremity 12 is immersed in the liquid in a vessel 10. The length of the tube 9 is adapted to the height of the vessel 10 to allow the bottom of the vessel 10

to be reached. A syringe 1 is connected to the drawing end piece 7 and a traction exerted on the piston 3. The liquid rises in the tube 9 and fills the chamber 25, the plug 26 being soaked with liquid. If it is ascertained that the chamber 25 is full of liquid or if the level of the liquid in the chamber 25 reaches a desired predetermined height, the free extremity 12 of the liquid is brought out, then a traction is exerted again on the piston 3 whereby air is admitted through the drawing extremity 12 into the tube 9, into the chamber 25, and through the plug 26, which brings about the formation of a foam in the female connector 6 and in the syringe body 2 (figure 11).

In order to administer the foam thus produced, one may replace the drawing end piece 7 with an injection needle 5 fitted or not with a permeable solid foam refining element as shown in figure 8 with reference to the first embodiment.

Nevertheless, the embodiment of figures 9 to 12 also allows a needle 5 to be connected to the extremity of the drawing end piece 7 as shown in figure 12 so that the foam recrosses the plug 26 during administration before passing into the needle 5. It is in fact ascertained that upon passing into this same plug 26 again, the foam is transformed being refined into a stable and homogeneous spumescent foam. In this embodiment, the plug 26 thus does duty on the one hand as a foaming means during drawing to form the foam in the syringe body 2 and, on the other hand, as a foam refining means during parenteral administration.

This embodiment is particularly advantageous in that it minimizes the number of manipulations of the operator and is simple and inexpensive. Moreover, the plug 26 enclosed in a chamber 25 is also well protected from contaminations.

Furthermore, in a variant of the invention, the device comprises at least one plug formed from a solid microperforated material (filter, grille, plate ...). In fact, in place of a cotton wad plug or other fibrous material, and of a foam block or other porous material, one can also consider using any other microperforated material capable of forming foaming means. Microperforated material means any material comprising numerous crossing passages such as those mentioned above, capable of forming



and/or refining a foam if it is crossed by the surfactant and the gas and/or by a foam already formed. By way of examples of microperforated material, one can use a filter, membrane, grille or plate made of metal or synthetic material, fitted with numerous submillimetre perforations or numerous such juxtaposed elements.

In all the embodiments, the drawing end piece 7 according to the invention thus comprises foaming means arranged outside the body 2 of the syringe 1, upstream of the extremity orifice of the male connector 4 of the syringe body 2 in the direction of flow of the liquid from the outside to the inside of the syringe body 2 when a traction is exerted on the piston 3.

As can be seen in figure 8, the device according to the invention may also incorporate a parenteral injection needle 5 of the foam previously formed inside the body 2 of the syringe. This needle 5 is fitted with a female connector 8 for its connection to the male connector 4 of the syringe body 2. The needle 5 also comprises a plug 23 of fibrous and/or porous and/or microperforated material, permeable to the foam, inserted in the female connector 8 so that this plug 23 is crossed by the foam coming from the syringe body 2 before passing into the channel of the needle 5 as such. This plug 23 may be formed from cotton - particularly from a hydrophilic cotton wad plug - or from any other fibrous and/or porous (soft or hard foam...) and/or microperforated material. The dimensions of the pores and/or the density of the material forming this plug 23 are adapted to permit the passage of the foam without breaking it across the plug 23, but whilst refining it, i.e. reducing the dimensions of the gas bubbles of the foam.

One thus obtains, in a surprising manner, at the extremity of needle 5, an extremely fine, dense and stable spumescent foam.

Such is the case, in particular, if the liquid used is a sclerosing composition comprising a surfactant sclerosing agent, for example, VEINOSCLEROL<sup>®</sup> marketed by the Laboratory KREUSSLER PHARMA, ROISSY, France or AETOXYSCLEROL<sup>®</sup> marketed by the Laboratory DEXO, NANTERRE, France or other. The invention is in particular applicable in the field of

sclerotherapy and allows a fine and stable foam of sclerosing composition to be injected extremely simply, quickly and inexpensively with great reliability.

It should be noted that the device according to the invention may be made completely from synthetic material (with the exception of the needle 5) and be throwaway, single-use (drawing end piece 7 and/or syringe 1 and/or needle 5 and/or vessel for liquid (10) or, in contrast, be at least partly reusable. Thus, in the embodiment of figures 4a to 4e, it is possible to provide for the vessel 10 to contain more than a single dose of liquid, the unit formed from the vessel 10 and from the drawing end piece 7 being capable of being re-used several times, with several different syringes, for several injections. Obviously, every precaution must be taken to preserve the sterility of the whole.

Moreover, the device according to the invention may also incorporate or be used with a reusable glass syringe. Furthermore, the various ways of creating and using the invention described above may be combined with each other.

The invention is also applicable with other compositions than the sclerosing compositions, and more generally for the parenteral administration of any cosmetic and/or therapeutic composition in the form of a foam made up of gas bubbles in a surfactant liquid.

## CLAIMS

1. Device for the production, inside the body (2) of a syringe (1), of a foam made up of gas bubbles in a surfactant liquid intended to be administered parenterally characterized in that it comprises a liquid drawing end piece (7) with formation of foam, this end piece (7) comprising:

- means of connection (6) of the end piece (7) to the body (2) of a syringe,
- an drawing extremity (11, 14, 16, 17, 12) adapted so that it may be place din contact with the liquid and permit drawing of the liquid under the effect of aspiration resulting from the manual operation of the piston (3) of the syringe (1),
- means (11, 14, 16, 17, 21), called foaming means, capable of bringing about the instantaneous formation of a foam from the drawn liquid and from the aspiration resulting from the manual operation of the piston (3) of the syringe (1), comprising means (11, 14, 16, 17, 19) to introduce a gas in contact with the drawn liquid to form the foam.

2. Device according to Claim 1, characterized in that the foaming means comprise at least one plug (11, 14, 16, 17, 21, 26) of fibrous and/or porous and/or microperforated material, permeable to the surfactant and to gas, and adapted so that it can be placed in contact with the drawn liquid and with a source of gas (11, 14, 16, 17, 19) and can deliver, under the effect of manual operation of the piston (3) of the syringe (1), the foam which is formed instantaneously upon crossing this plug (11, 14, 16, 17, 21, 26) in a conduit 924) or a cavity (20, 25) communicating with the inside of the body (2) of a syringe (1) connected to the drawing end piece (7) by means of connection (6).

3. Device according to Claim 2, characterized in that a plug (11, 21, 26) is formed from cotton - particularly from a hydrophilic cotton wad plug -

4. Device according to one of Claims 2 and 3, characterized in that a plug (14, 16, 17, 26) is formed from a porous solid material block - particularly a hard or soft solid foam -

5. Device according to one of Claims 1 to 4, characterized in that the drawing end piece (7) comprises a tube (9, 18) one extremity of which is in communication with the body (2) of the

syringe through means of connection (6).

6. Device according to Claims 2 and 5, characterized in that the foaming means comprise a plug (11, 14, 17) linked to the extremity of the tube (9, 18) opposite the means of connection (6) to form said drawing extremity.

7. Device according to one of Claims 1 to 6, characterized in that this plug (14) is spongy and adapted to draw instantly through soaking in the liquid and capillary action a predetermined quantity of liquid.

8. Device according to Claim 7, characterized in that the plug (14) is adapted to present whilst dry dimensions in width less than those of a neck (15) of a vessel for liquid (10) so as to permit its introduction into such a vessel (10) and, once soaked with liquid, dimensions in width greater than those of the neck (15) so as to prevent its untimely extraction out of the vessel (10).

9. Device according to one of Claims 1 to 8, characterized in that the drawing end piece (7) comprises a chamber (25) placed between the means of connection (6) and the drawing extremity in communication with the means of connection (6) and the drawing extremity and enclosing at least one plug (26) of fibrous and/or porous and/or microperforated material (26).

10. Device according to one of Claims 1 to 9, characterized in that it comprises a vessel (10) for liquid.

11. Device according to one of Claims 1 to 10, characterized in that it comprises a syringe (1).

12. Device according to one of Claims 1 to 11, characterized in that the means of connection (6) comprise a cavity (20) receiving the liquid drawn from the drawing extremity and in that the foaming means comprise a gas outlet (19) into the cavity (20).

13. Device according to Claim 12, characterized in that the cavity (20) receives the liquid through an orifice (22) issuing into the cavity (20) and in that the effective cross-section of the gas outlet (19) is less than that of this orifice (22).

14. Device according to one of Claims 12 and 13, characterized in that the foaming means comprise a plug (21) placed in the cavity (20).

15. Device according to one of Claims 1 to 14, characterized in that the drawing extremity is fitted with a filter (13) adapted to prevent the aspiration of solid impurities.

16. Device according to one of Claims 1 to 15, characterized in that it presents itself in the form of a kit of different parts packed together comprising a drawing end piece (7) and a syringe (1) and/or a vessel (10) for liquid.

17. Device according to one of Claims 1 to 16, characterized in that it also comprises an injection needle (5) for the foam fitted with means of connection (8) to the body (2) of a syringe (1) and in that this needle (5) comprises at least one solid element (23) permeable to foam - particularly a plug (23) of fibrous and/or porous and/or microperforated material inserted in the means of connection (8) and adapted so that it can be crossed by the foam before passing into the channel of the needle (5).

18. Device according to Claim 17, characterized in that the solid element (23) is formed from a cotton plug - particularly from a hydrophilic cotton wad plug.

19. Device according to one of Claims 1 to 18, characterized in that the liquid is a composition intended for sclerotherapy comprising a surfactant sclerosing agent.